

## REMARKS

The Examiner is thanked for entering the Amendment filed June 10, 2010.

Claims 15 to 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wright as evidenced by Shapiro et al. (Shapiro) in view of Kunz et al. (Kunz). Claims 16 and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wright as evidenced by Shapiro in view of Kunz as applied to claims 15 and 18 further in view of Panotti.

In response to the rejections of record, claims 15 to 18 have been cancelled, and new claims 19 to 22 are being submitted, in order to patentably distinguish the Applicant's invention over all the prior art references.

New claim 19 substantially corresponds to previous claim 15, except that the term "comprises" at line 13 of canceled claim 15 has been replaced with the transitional phrase "consists of".

Thus, the presence of essential oils is excluded from new claim 19. In other words, essential oils may not be included in the Applicant's compositions along with the components recited in canceled claims 15 to 18.

The rejections of record have been entered have relied extensively on the Shapiro publication. Shapiro discloses the antimicrobial activity of different essential oils and essential oil components which are excluded from the newly presented claims.

More specifically, Shapiro discloses the different MIC (Minimal Inhibitory Concentration) and MBC (Minimal Bactericidal Concentration) and possible synergic or antagonist effects between several

molecules.

The oils included in the claimed mouthwash (vegetal oils, mineral oils, aliphatic oils) are not essential oils or essential oil components that are disclosed by Shapiro (peppermint, sage, tea tree, eugenol, thymol, and so on).

The difference between the above described types of oils is a fundamental one both from a chemical and functional standpoint.

In fact, as suggested by their definition, essential oils are concentrated lipophyl substances containing plant aromatic volatile compounds. Their components may also be obtained by synthesis and in general are used in small concentrations as active principles.

The non essential oils, pointed out in the newly presented claims have many different origins, such as vegetable, derivatives from mineral oil (petrol), synthesis compounds and their use is mainly as excipients in pharmaceutical and cosmetic formulations, even in high concentrations.

In the claimed invention the non essential oils constitute the base of the claimed product and they are present in significant amounts and, most importantly, are stably emulsified by suitable oil in water (O/W) emulsifying agents.

Shapiro only teaches the use of essential oils as active principles in a very limited amounts.

In fact, on page 207, column 1, line 10, Shapiro discloses, as a "cut-off" value, a concentration of 0.6% beyond which it is not possible and safe to use these essential oil active principles in compositions for oral hygiene.

On the contrary, the Applicant's oil must be

present in much greater amounts, that is from 5% to 40% as pointed out in new claim 19.

These non essential oils, in an emulsified condition, constitute a matrix providing the claimed compositions with long duration tooth protective and adhesive characteristics.

The MIC measurements for the claimed compositions have demonstrated that the emulsified matrix does not passivate the most common antibacteric agents used in oral hygiene (chlorhexidine, hexetidine, cetylpyridinium chloride and triclosan).

The Examiner pointed out in the Office Action that: "In regard to Applicant's arguments pertaining to Pianotti, Applicant's claims recite the transitional language of "comprising" which is open language and therefore other components not recited by the instant claims are encompassed by the instant claims. AS noted above, the newly presented claims exclude the presence of essential oils.

The Applicant's non essential oils do not have any antibacteric action per se, but are indispensable for extending the time during which the antibacteric substances or other principles, which are present in the Applicant's compositions, are active.

The Wright reference lacks any teaching that would cause a skilled worker in the art to combine that reference with Shapiro, Kunz, or Pianotti.

In fact Wright teaches the use of a C12-C16 halogenated cationic compound which also has an antibacterial action, as an emulsifying substance. An example of such an antibacterial substance is cetylpyridinium chloride. This compound is a water soluble compound which is actually freely soluble in

water. The cetylpyridinium chloride in Wright is included in the oil phase and new claim 19 excludes this component of the Wright composition from the oil phase

Accordingly, Wright does not suggest the use of oil-soluble antibacterial substances in the oil phase. On the other hand, a main feature of Applicant's mouthwash composition, is that Applicant's emulsion provides an improved binding of the product to the buccal mucosa, while providing a protective film which is only slightly removed by water rinsings or by the user's saliva. This provides the claimed compositions with a prolonged duration of activity.

The prolonged activity feature of the claimed compositions is neither disclosed nor suggested as a main feature by the compositions of the Wright patent.

Pianotti discloses an antimicrobial composition in the form of a mouthwash comprising a water-alcohol phase in which essential oils are dissolved, these essential oils comprising thymol, eucalyptol, methylsalicylate, mentol.

The claimed mouthwash composition, as pointed out in new claim 19, does not comprise essential oils but vegetable oils, mineral oils, aromatic oils and aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons.

Pianotti's mouthwash composition and that of the presently claimed mouthwash composition, operate in a very different manner. The claimed composition provides an oil film that adheres to the surface of the mouth cavity whereas the Pianotti mouthwash is not designed or adapted to provide this strong

adhesion property, since it is a traditional mouthwash composition which is easily removed when the inner mouth cavity is rinsed.

With respect to Kunz, this patent discloses and claims compositions for continuously transporting a bioactive agent through a biologic membrane. On the contrary, Applicant's mouthwash composition of new claims, is an emulsion which must adhere to the oral mucosa (and is not transported therethrough) for a long time to continuously provide an antibacterial action.

Kunz does not teach or suggest the use of antibacterial or disinfecting agents and the like, as it is limited to the delivery of bioactive agents or nucleic acids through a biologic membrane.

The Kunz composition may be delivered orally. However, such an oral delivery actually involves swallowing and ingesting the Kunz composition, whereas Applicant's mouthwash composition is used as a conventional mouthwash, that is only for rinsing the oral or buccal cavity and it is neither swallowed nor ingested.

New claims 19 to 22 define subject matter that is not made obvious over the prior art references, and allowance thereof is respectfully solicited.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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